

## REMARKS/ARGUMENTS

### General Remarks

All of the presently pending method claims expressly require that the device is used *from a position proximal of the topmost tissue layer* (e.g., conjunctiva or stratum corneum). Thus, the device operates in a manner distinct from a syringe in which the device is inserted into the tissue that is to be clarified. Similarly, the optical portion *delivers the light from the proximal position* in a manner such that the light will pass through an opening (or topmost layer) into or below an area of clarified tissue.

Also, with respect to Chan et al., applicant points out that *Chan et al. use deep infrared light* in their devices and methods (e.g., column 6, lines 35 et seq.: any wavelength within the continuous range of 0.9-20 microns [*i.e.*, 900 nm-2000 nm]), while the present subject matter is drawn to visible light. Such difference is not trivial as all of the claimed methods are drawn to tissue clarification (*light scattering is a function of the wavelength*) for visible light delivery.

### 35 USC § 112

Claims 70-85 were previously rejected under 35 USC § 112, first paragraph, as lacking enabling description of "...how to deliver an effective amount..." of clarifying agent. *Claims 70-85 are canceled and the rejection is therefore moot.*

### 35 USC § 103

Claims 70-85 were rejected under 35 USC § 103 as being obvious over Eppstein (U.S. Pat. No. 6,527,716) in view of Chan (U.S. Pat. No. 6,275,726). *Claims 70-85 were canceled and the Examiner's rejection is therefore moot.* Nevertheless, Eppstein and Chan are addressed below to point out why the new claims are not obvious over these references.

(I) Among other elements, new claim 86, and claims 87-92 by virtue of their dependence on new claim 86, all expressly require a step of "...providing a *device that includes a pore forming portion*, wherein the *pore forming portion is coupled to a delivery portion and an optical portion...*", a step of creating "...an *opening in a conjunctiva...*", and further

expressly require that "...the *clarifying agent enhances optical transparency of the sclera* to thereby form an area of clarified sclera..." These elements are clearly not taught by either of Chan and Eppstein. Therefore, there must be a suggestion or motivation in the Chan and/or Eppstein reference to modify their teachings such as to arrive at the subject matter as presently claimed. However, the opposite is the case.

First, *neither Eppstein nor Chan teach formation of an opening in a conjunctiva. A conjunctiva is inconsistent with a stratum corneum.* It should be pointed out that the differences between a conjunctiva and the stratum corneum are substantial, and that the conjunctiva is not just an obvious variant of the stratum corneum and *vice versa*. Among other things, the stratum corneum comprises dead cells while the conjunctiva comprises living cells. Furthermore, the stratum corneum is an *optically dispersive tissue* whereas the conjunctiva is an *optically clear tissue*. Still further, as the eye already has a transparent point of access for delivery of optical energy (e.g., through lens), a person of ordinary skill in the art *would not be motivated to clarify an area of sclera* as presently claimed.

Furthermore, neither Eppstein nor Chan teach a combination device in which *a pore forming portion is coupled to a delivery portion and an optical portion, let alone to use such a device from a position proximal to the sclera.* On the contrary, Chan teaches chemical abrasion, mechanical debridement, etc. to remove the stratum corneum, which at least teaches away, if not even against new claims 86-92. Similarly, Eppstein teaches at best a combination of a pore forming device with a delivery device, which at least teaches away, if not even against new claims 86-92.

Third, *neither Eppstein nor Chan teach application of a clarifying agent to enhance optical transparency of the sclera.* Once more, a *sclera* (i.e., the 'white in an eye') *is entirely inconsistent with a dermal tissue underlying the stratum corneum.*

(II) New claim 93, and claims 94-100 by virtue of their dependence on new claim 94, all expressly require a step of "...providing a *device that includes a driver portion*, wherein the *driver portion is coupled to a delivery portion and an optical portion*...", a step of "...*using the driver portion to drive the clarifying agent across the permeability barrier*...", and further expressly require using the "...optical portion *non-invasively to deliver light* such that the *light*

*passes through the permeability barrier to an area within or below the area of clarified target tissue...*", and "*...the device does not penetrate the permeability barrier and the target tissue ...*" Again, these elements are clearly not taught by either Chan or Eppstein.

In contrast, both *Chan and Eppstein expressly teach that the permeability barrier is removed (by formation of a pore or ablation), which is entirely inconsistent with the presently pending claims 93-100*. Still further, Chan teaches application of light to the target tissue by applying light directly to the clarified tissue *but not through the permeability barrier* as presently claimed. Clearly, Chan and Eppstein teach against the subject matter as presently claimed in added claims 93-100. Therefore, and at least for these reasons, added claims 93-100 should not be held obvious over Chan in view of Eppstein.

(III) Similarly, new claim 101, and claims 102-105 by virtue of their dependence on new claim 101, all expressly require a "*...device that includes a pore forming portion...coupled to a delivery portion and an optical portion...*" and a step of "*...using the optical portion non-invasively to deliver visible light through the stratum corneum or the opening to an area within or below the area of clarified tissue such that the light passes through the stratum corneum to an area within or below the area of clarified tissue...*". As above, these claims also expressly require that "*...the device does not penetrate the stratum corneum and the tissue below the stratum corneum...*"

Again, these elements are clearly neither taught nor suggested. With respect to the combination of a pore forming portion, a delivery portion, and an optical portion, the same arguments as provided above apply. Furthermore, the applicant points out that *Chan uses infrared light* as can be clearly taken from column 5, lines 35 *et seq.* Finally, the *light in Chan does not pass through the stratum corneum as that layer is abraded* or as the light is passed from the dermis side (*i.e.*, opposite side). In these respects, *Chan clearly teaches away* from the subject matter as presently claimed, and Eppstein has no teachings to remedy this shortfall. Consequently, added claims 101-105 should not be held obvious over Eppstein and Chan.

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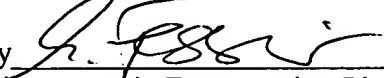
Nemati, Babak

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In view of the present amendments and arguments, the applicant believes that all claims are now in condition for allowance. Therefore, the applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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